# Premarket Review Considerations for Reprocessed SUDs

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**Office of Device Evaluation**

# Classification

May 1976 premarket process begins

- Three classes I, II, III
  - Class I (least risk)
  - Class II
  - Class III (greatest risk)

**All devices grouped by generic type into one of the three classes**

# Important Dates for Reprocessors:

| Premarket Submission Due Dates | | |
|---|---|---|
| | Due By: | Must be Cleared or Approved by: |
| Class III | 2/14/2001 | 2/14/2002 |
| Class II non-exempt | 8/14/2001 | 8/14/2002 |
| Class I non-exempt | 2/14/2002 | 8/14/2002 |

# Devices Excluded from Reprocessing Enforcement Strategy

- Permanently implanted pacemakers (see Compliance Policy Guide, 7124.12)
- Hemodialyzers (see specific guidance)
- Opened but unused devices
- SUDs reprocessed by health care facilities that are NOT hospitals (however, enforcement may be expanded to cover in the future)

# Premarket Requirements

- Premarket Notification (510(k))
  - 21 CFR Part 807
- Premarket Approval (PMA)
  - 21 CFR Part 814

# 510(k) or PMA?

- Class III: Submit a premarket approval application (PMA).
- Class II:  Submit a premarket notification (510(k)), unless device is exempt from premarket requirements.
- Class I: no 510(k) or PMA is required except for “reserved” class I devices.

# Examples of Reprocessed SUD's

| Device | Class |
|---|---|
| Surgical Saw Blades | I |
| Electrophysiology Catheters | II |
| Cardiac Ablation Catheters | III |

**Additional devices listed at http://www.fda.gov/cdrh/reuse/1168a.html**

# PMA vs. 510(k)

- PMA
  - valid scientific evidence
  - risk/benefit analysis
- 510(k)
  - substantial equivalence

# Reprocessors of SUDs Are Considered to Be Manufacturers

- All premarket submissions to be handled the same
  - No special considerations or allowances, e.g., expedited review or reduced testing requirements
  - No extraordinary review criteria or supplemental evaluations necessary

# Specific Considerations for PMA Applications

- Data to demonstrate safety & effectiveness
- Manufacturing processes (including validation)
- Pre-approval inspection required
- Manufacturing process in compliance with QSR

# 510(k) Submission Describes a Device Not a Process

- Device adequately described & characterized (through testing)
- Demonstrate that reprocessed SUD is substantially equivalent to predicate device

# 510(k) Submission Describes a Device Not a Process

- Manufacturing processes assessed through QSR and FDA inspections
- Sterility an important device characteristic

# Sterilization and Disinfection Information Should Include

- Description of decontamination/ cleaning processes
- Description of validation method for cleaning and sterilization/disinfection
  - Simulated use protocol should be developed
  - Reflect worse case conditions
  - Manipulation and simulated use in biological soil

# Sterilization and Disinfection Information Should Include

- Endpoints for cleaning and sterilization/disinfection
- Sterility assurance level
- Conformance with appropriate recognized standards
- Description of packaging materials

# Performance Tests

- Device specific - check for appropriate guidance document
- Additional tests may be needed to assess effects of reprocessing
- Test devices that have gone through simulated use protocol
- Include descriptions of tests performed to determine product release, provide pass/fail criteria

# Biocompatibility Tests

- If needed for OEM device, will be needed for reprocessed devices
- Cleaning and sterilization agents may adversely affect device materials and biocompatibility

# Biocompatibility Tests

- Testing should be done under worst case conditions (maximum times device is to be reprocessed; include exposure to simulated use).
- See specific ODE guidance document on bicompatibility testing.

# Shelf Life Tests

- If needed for OEM device, will be needed for reprocessed device
- Evaluate and document stability under worse case conditions
  - should reflect exposure to simulated use protocol and maximum number of times device can be reprocessed

# Labeling

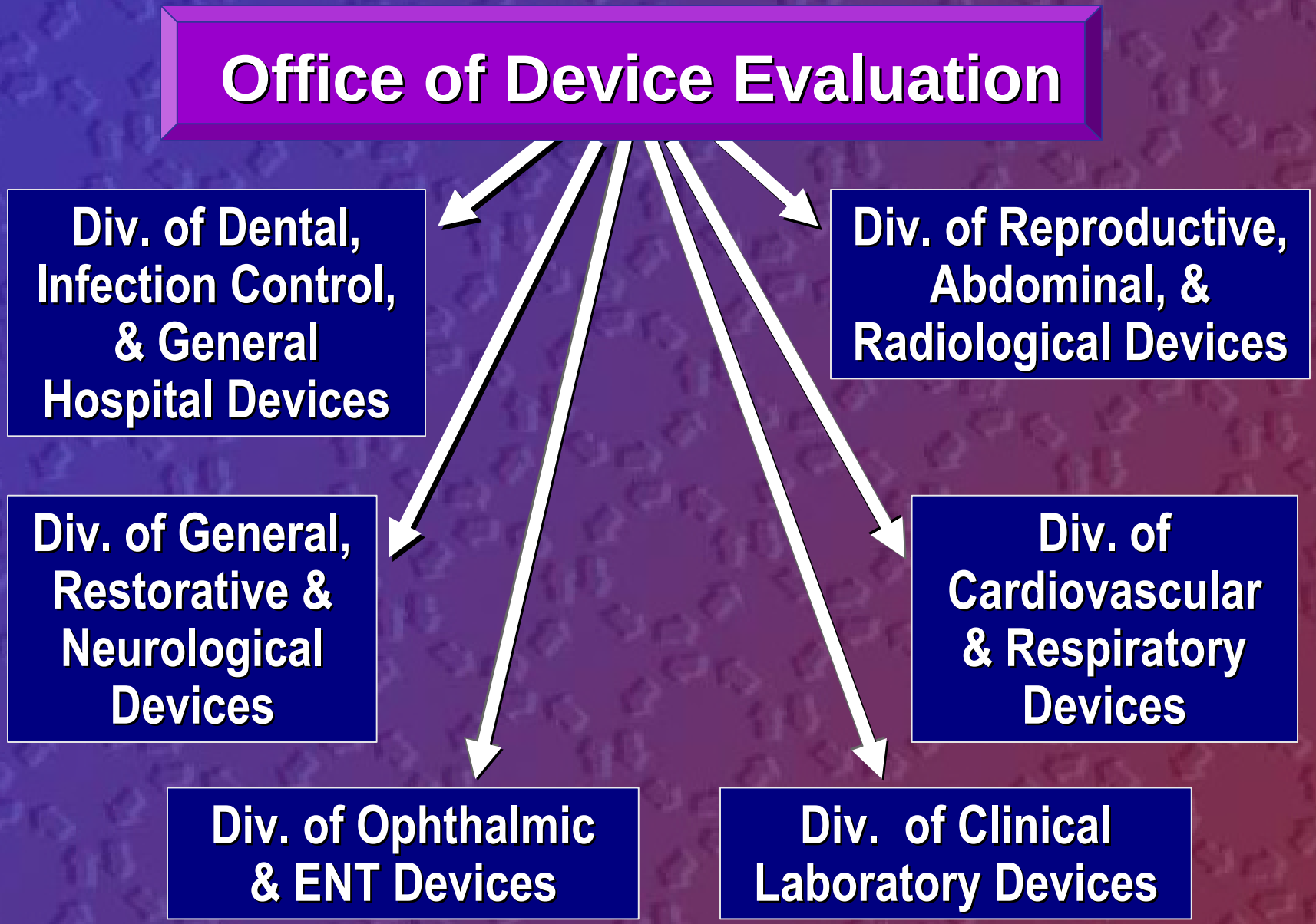
- Labeling (device description, indications for use, adequate directions for use) are required for all devices cleared under 510(k).
- Labeling must include reprocessor's name, address and other contact information.
- Labeling must be included with the device (not on file at the hospital or user facility).

# Can One 510(k) Cover Multiple Devices?

- Yes, if devices would be included in one 510(k) by the OEM
- Bundled devices w/same indications for use
- Reprocessors could propose specifications for a device that encompasses models from more than one OEM

# To Expedite Review

- In cover letter identify as a premarket submission for reprocessed SUD.
- Consider using special and abbreviated 510(k)s.
- Submit master files if information can be used in multiple submissions.
- Pre-submission meetings and teleconferences may be useful.


Office of Device Evaluation
Div. of Dental, Infection Control, & General Hospital Devices
Div. of Reproductive, Abdominal, & Radiological Devices
Div. of General, Restorative & Neurological Devices
Div. of Cardiovascular & Respiratory Devices
Div. of Ophthalmic & ENT Devices
Div. of Clinical Laboratory Devices

# Contact Persons

- Coordination of Reuse Policy in ODE (premarket issues only)
  - Philip J. Phillips (301) 594-2022
  - Timothy A. Ultatowski (301) 443-8879
  - Heather Rosecrans (301) 594-1190
  - Barbara Zimmerman (301) 594-2036

# Guidance Documents

- Specific for Reprocessors
  - "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals"

    www.fda.gov/cdrh/reuse/1168.html
  - "Frequently Asked Questions on Reuse of Single Use Devices"

    www.fda.gov/cdrh/reuse/reuse-faq.shtml

# Guidance Documents

- Specific for Reprocessors
  - Letter to Hospitals Re: Reprocessing of Single Use Devices - 4/23/01 www.fda.gov/cdrh/reuse/042301_reuse.html
  - Compliance Policy Guide (CPG 7124.16) Section 300.500. Reuse of Medical Disposable Devices - 9/24/87 www.fda.gov/cdrh/comp/ cpgreuse.pdf

# Guidance Documents

- Biocompatibility
  - "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'"

    www.fda.gov/cdrh/g951.html

# Guidance Documents

- Reusable Devices
  - "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance"

    www.fda.gov/cdrh/ode/198.pdf

# Guidance Documents

- Reusable Devices
  - "Questions & Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities"

www.fda.gov/cdrh/ode/ 1198.html

# Guidance Documents

- Use of Standards in 510(k)s
  - "Use of Standards in Substantial Equivalence Determinations"

    www.fda.gov/cdrh/ode/guidance/1131.html
  - "Guidance on the Recognition and Use of Consensus Standards"

    www.fda.gov/cdrh/modact/ k982.html

# Guidance Documents

- Use of Standards in 510(k)s
  - "Frequently Asked Questions on Recognition of Consensus Standards"

www.fda.gov/cdrh/modact/faqost.html

# Guidance Documents

- Abbreviated and Special 510(k)s
  - "A New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications"

    www.fda.gov/cdrh/ode/parad510.html
  - "Frequently Asked Questions on the New 510(k) Paradigm"

    www.fda.gov/cdrh/ode/ 92_a.html

# Guidance Documents

- Sterlization
  - "Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA"

www.fda.gov/cdrh/ode/guidance/361.pdf